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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/701,908 | 01/22/2001 | Christoph Heller | CU-2409 VE | 1606 |
| 7590 03/17/2004 | | | EXAMINER | |
| Vangelis Economou | | | OLSEN, KAJ K | |
| Ladas & Parry | | | ART UNIT | |
| Suite 1200 | | | PAPER NUMBER | |
| 224 South Michigan Avenue | | | 1753 | |
| Chicago, IL 60604 | | | DATE MAILED: 03/17/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/701,908 | Applicant(s) HELLER ET AL. | |
| | Examiner Kaj Olsen | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: Page 4 of the specification describes the invention in part by referring to the claims by number. Please note that claim numbers are subject to change over the course of the examination and the examiner recommends the applicant remove any reference to claims by number from the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg et al (USP 6,086,825).

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4. With respect to claim 1, Sundberg discloses an electrophoretic device that comprises a plurality of separation channels 78 that can be separately loaded with samples via a shared injection channel 76 where each area of the injection channel near the individual separation channels constitutes a sample channel area (fig. 7 and col. 9, lines 30-54). The injection channel intersects the separation channels (fig. 7). It would appear that said intersection would read on the term "crossing points" giving the claim language its broadest reasonable interpretation. In other words, it is not necessary for channel 78 to cross channel 76 because channel 76 clearly crosses channel 78. The ends of channel 76 have electrodes for providing electroosmotic (i.e. electrokinetic) flow of the fluid through the channel (col. 6, lines 47-58). Each of the intersections between the injection channel and the separation channel constitutes an application area giving the claim language its broadest reasonable interpretation.

5. With respect to claim 5, see fig. 3 and 7 in conjunction with col. 6, lines 59-64 and col. 9, lines 40-43).

6. With respect to claim 6, making the chip disposable is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

7. With respect to claim 7, the device of Sundberg could be utilized as part of an unclaimed, undefined analyzer. A pipette 20 or pin 38 would appear to constitute a micro-dispenser of fluids.

8. With respect to claim 8 (those limitations not covered above), electrophoretic separation takes place along the separation channels 78 (col. 9, lines 30-43).

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9. Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg (USP 6,086,825) with evidence provided by Parce et al (USP 5,958,203).

10. Sundberg specifies all the limitations of claim 9, but did not explicitly specify anything concerning electrically concentrating samples prior to the separation through the separation channels. Parce in an alternate sample injection device for a microfluidic device evidences that when electrokinetic means are utilized for sample transport (as Sundberg teaches utilizing), the ionic samples in question inherently become concentrated in parts because of the application of electrokinetic transport means (paragraph bridging col. 17 and 18). Because Sundberg relies on the analogous electrokinetic flow taught by Parce, then Sundberg would also inherently concentrate the sample prior to injection into the separation channels.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al (USP 5,958,203) in view of Sundberg (USP 6,086,825).

14. With respect to claim 1, Parce discloses an electrophoretic device that comprises a separation channel 110 that intersects at a crossing point an injection channel 112 (fig. 1, col. 6, lines 46-65). Parce further discloses electrodes for the purpose of generating an electric field in the injection channel (paragraph bridging col. 6 and 7). Parce does not explicitly disclose the presence of a plurality of separation channels intersecting with the injection channel. Sundberg teaches in an alternate electrophoretic device where an injection channel 76 can be utilized to supply sample to a plurality of separation channels intersecting with the injection channel (see discussion above with respect to this reference). Utilizing a plurality of separation channels for a given sample injection would allow one to perform many separations simultaneously thereby reducing analysis time. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Sundberg with the device of Parce in order to allow one to perform many separations simultaneously thereby reducing analysis time.

15. With respect to claims 2-4, see element 160 in figure 6A, which is a channel expansion that the applicant contends constitutes a molecular trap.

16. With respect to claim 5, see Parce, col. 1, lines 15-50 and col. 6, lines 46-50.

17. With respect to claim 6, making the chip disposable is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

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18. With respect to claim 7, the device of Parce in view of Sundberg could be utilized as part of an unclaimed, undefined analyzer (see similar rejection above for Sundberg).

19. With respect to claim 8 (those limitations not covered above), Sundberg teaches the use of micro-dispensers (20, 38) for introducing samples into an injection channel (col. 4, lines 65-67 and col. 5, lines 32-45) and Parce teaches performing electrophoresis on the samples in the separation channels (col. 6, lines 54-65).

20. With respect to claim 9, see paragraph bridging col. 17 and 18 of Parce.

Response to Arguments

21. Applicant's arguments filed 12-08-2003 have been fully considered but they are not persuasive. Applicant urges that Sundberg does not qualify as prior art because it has a filing date of March 23, 1999, which is after the priority date of the instant invention. The applicant fails to note that Sundberg is a continuation of an earlier application and thereby has an effective filing date of June 6, 1997, which does qualify as prior art under 35 U.S.C. 102(e).

22. Applicant also urges that Sundberg fails to disclose a number of the limitations. In particular, applicant urges that the separation channels cannot be separately loaded with sample. To support this erroneous conclusion, applicant cites col. 9, lines 43-60 of Sundberg. However, the examiner does not see anything about this cited passage that supports the applicant's position. This section merely talks about the samples are wicked into the respective channels. Sundberg would appear to be as capable of separately loading samples into the separation channels as the instant invention is.

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23. Applicant also urges that there is no application area provided at the crossing points.

However, looking to the specification, all the application area is initially defined as is the area adjacent the intersection (see sentence bridging pp. 9 and 10 of the specification). Sundberg inherently has an area adjacent to the intersection as well (e.g. where reference character 76 points to in fig. 7). Hence, Sundberg possesses an application area giving the claim language its broadest reasonable interpretation.

24. Applicant also urges that the injection channels do not intersect the separation channels.

However, the examiner dealt with this issue at the end of paragraph 9 of the previous office action. To further clarify, because channel 76 goes across each channel 78, it thereby intersects each of these channels. The examiner does not believe that there is anything inherent in the applicant's use of the term "intersects" that implies that the separation channels must extend beyond the injection channel in order for an intersection of the separation channel. Hence the examiner is giving the claim language its broadest reasonable interpretation, and applicant has not specifically refuted this interpretation of the claim language.

25. Applicant also specifically points out their belief that Guzman differs from the instant invention in a number of ways. For the record, the examiner neither agrees nor disagrees with the applicant's conclusion concerning Guzman, because these arguments are moot in view of the fact that the reference is not available to the examiner as prior art. The examiner's silence with respect to these arguments should not be interpreted as an agreement with the applicant.

26. With respect to the rejections utilizing Parce, applicant urges that there is only a single separation channel. The examiner agrees, but the rejection was based on the combination of Parce and Sundberg with Sundberg teaching the obviousness of having a plurality of separation

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channels for each injection channel. Applicant does not appear to have specifically refuted the combination of the references. Applicant also urges that Parce does not teach the inclusion of an application area. This is not persuasive for the same reason discussed above with Sundberg.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj Olsen Ph.D.
Primary Examiner
AU 1753
March 9, 2004